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EXAMINER	
RAPILLO, KRISTINE K	
ART UNIT	**PAPER NUMBER**
4137	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,900	MAXWELL ET AL.	
	Examiner	Art Unit	
	Kristine K. Rapillo	4137	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 – 24 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 –24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (U.S. Patent No. 6,314,384) in view of Hacker.

In regard to claim 1, Goetz et al. teaches a medical information processing method comprising: compiling said data into a data processing system (column

12, lines 56 – 59); identifying at least one item of consequential information from the following group: a side effect of the medication, a drug-drug interaction of the medication, and a therapeutic class of the medication (column 12, lines 1 – 3 and lines 22 – 24; column 6, lines 56 and 59) where the Examiner interprets the therapeutic class to be the 'indication' of the medication (i.e. antihistamines/allergies); inserting said at least one item into the data processing system (column 9, lines 14 – 23); enabling a third-party user to access said information and item from a location remote from the location of said data processing system (column 8, lines 62 – 65); and facilitating the display of said item to the user (column 11, lines 31 – 33 and Figure 23).

Goetz et al. fails to teach gathering medication specific data for the medication of a patient from a plurality of independent sources.

Hacker teaches a method of gathering medication specific data for the medication of a patient from a plurality of independent sources. One example of Hacker's invention describes the transfer of an electronic medical record from the military before the patient is discharged from the military (column 10, line 60 through column 11, line 1).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method of facilitating a display of said item to the user as taught by Hacker with the motivation of allowing patients and health care providers (i.e. doctors, pharmacists) access to a patients medical records via a network (column 6, lines 20 – 24).

In regard to claim 2, Goetz et al. teaches a method, as per claim 1, for medical information processing wherein step (f) includes the step of facilitating the display of the side effect of the medication, which is severe and probable, and the therapeutic class of the medication to the user (column 10, line 60 through column 11, line 1). Goetz et al. illustrates in Figure 20 a series of special instructions, which include side effects of a medication. In addition, Figure 23 shows a drug-drug interaction with the potential outcomes of a patient taking both medications.

In regard to claim 3, Goetz et al. teaches a method, as per claim 2, wherein: step (c) includes identifying a disease contraindication of the medication (column 15, lines 41 – 45); and step (f) includes facilitating the display of the disease contra indication of the medication to the user (column 15, lines 41 – 45 and Figure 23). The Examiner has interpreted disease contraindications as the inadvisability of prescribing a medication due to severe side effects, duplicate medications from the same therapeutic class, and drug-drug interactions.

In regard to claim 4, Goetz et al. teaches a method, as per claim 1, wherein step (e) further comprises: assigning the user an identification code (column 2, lines 55 – 58) and assigning the user a pass code (column 10, lines 28 – 31 and Figure 13).

Goetz et al. fails to teach a method wherein upon entry of an identification code and pass code, comparing the entered identification code and the pass

code to the assigned identification code and the assigned pass code to authorize access to the information and item.

Hacker teaches a method wherein upon entry of an identification code and pass code, comparing the entered identification code and the pass code to the assigned identification code and the assigned pass code to authorize access to the information and item (column 7, lines 24 – 26 and lines 43 – 50].

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein upon entry of an identification code and pass code, comparing the entered identification code and the pass code to the assigned identification code and the assigned pass code to authorize access to the information and item as taught by Hacker with the motivation of allowing patients complete control of their medical records by enabling the patient to determine who has access to their records, as well as the level of access (column 7, lines 60 through column 8, line 3].

In regard to claim 5, Goetz et al. teaches a method, as per claim 1, wherein step (a) the medication specific data further comprises at least one of the items of data selected from the following group: a name of the medication; an administration dose of the medication; a name of a health care provider that prescribed the medication; an original date of a prescription for the medication; a date of exhaustion of the prescription for the medication; a set of instructions for administering the medication; and compliance information for the medication

(column 6, line 56).

In regard to claim 6, Goetz et al. teaches a method, as per claim 1, wherein: in step (a) the medication specific data includes information indicative of patient usage of prescribed medications (column 6, lines 46 – 47) and in step (c) the consequential information includes information regarding the indicated patient usage of prescribed medications (column 6, line 58 - 59).

In regard to claim 7, Goetz et al. teaches a method, as per claim 1, wherein: step (e) includes enabling a selected class of users to access less than all of the consequential information (column 10, lines 28 – 31).

In regard to claim 8, Goetz et al. teaches a method of profiling the medication history of a patient, comprising: integrating said information into a data system that is accessible on-line (column 2, lines 59 – 67 and column 6, lines 22 – 28) where PAN (Personal Area Network) can be used to connect to a higher level network and the internet, comparing the patient's medication information to a drug-drug interaction database in order to identify severe and moderate drug-drug interactions (column 15, lines 41 – 45 and lines 53 – 67), and comparing the patient's medication information to a disease contraindication database in order to identify severe and moderate disease contra indications (column 15, lines 41 – 45 and lines 53 – 67); and compiling in the data system the identified drug-drug interaction and category of severity of the drug-drug

interaction and the identified disease contraindication and category of severity of the disease contra indication (column 15, lines 32 - 40).

Goetz et al. fails to teach a method of collecting the patient's medication information from medication distribution information of a plurality of health care providers and facilitating access to information in said data system by a user through an on-line connection.

Hacker teaches a method of collecting the patient's medication information from medication distribution information of a plurality of health care providers and facilitating access to information in said data system by a user through an on-line connection (column 8, lines 4 – 13) where a patient has allowed access to both a pharmacist and physician who can therefore collect the information pertinent to their function; and of facilitating access to information in said data system by a user through an on-line connection (column 11, lines 7 – 12).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method of collecting the patient's medication information from medication distribution information of a plurality of health care providers and facilitating access to information in said data system by a user through an on-line connection as taught by Hacker with the motivation of enabling physicians and other health care providers the ability to determine if any drug-drug interactions or side effects are likely, based upon the information contained in the electronic medical record (column 11, lines 19 – 31).

In regard to claim 9, Goetz et al. teaches a method, as per claim 8, further comprising the step of facilitating the display of the patient's medication information to a user accessing the data system by providing a patient identification number and a patient pass code (column 2, lines 55 – 58; column 10, lines 28 – 31; and Figure 13).

In regard to claim 10, Goetz et al. teaches a method, as per claim 8, wherein the patient's medication information further comprises at least one item of information taken from the following group: a name of a medication; an administration dose of the medication; a name of a health care provider that prescribed the medication; an original date of a prescription for the medication; a date of exhaustion of the prescription for the medication; a set of instructions for administering the medication; and compliance information for the medication (column 6, line 54 – 62).

In regard to claim 11, Goetz et al. teaches a method, as per claim 8, further comprising the step of facilitating display of severe and moderate drug-drug interactions and severe and moderate disease contra indications to a user entering a health care provider identification number and pass code (column 12, lines 56 – 64). The examiner interprets and OTC (Over-the-Counter) drug database to serve in the same capacity as a prescription drug database.

In regard to claim 12, Goetz et al. teaches a method, as per claim 8, further comprising: determining indicated patient usage of the medications (column 6, 45 –47).

In regard to claim 13, Goetz et al. teaches a method, as per claim 8, further comprising: enabling a health care provider to submit a proposed new medications (column 10, lines 50 – 67); and comparing the proposed new medication to both the databases to identify further drug-drug interactions and disease contra indications (column 11, lines 29 - 33).

In regard to claim 14, Goetz et al. teaches a method, as per claim 8, wherein: a selected class of users is facilitated access to less that all of said information (column 10, lines 28 – 31).

In regard to claim 15, Goetz et al. teaches a method of generating a medical profile for a patient, comprising: (c) facilitating the display of the patient medication information and profile information to a user (Figures 9 - 12) and (d) controlling the display of said patient medication information and profile information by providing an identification code and pass code to the user that

must be entered for the user to gain access to the information (column 2, lines 55 – 58; column 10, lines 28 – 31; and Figure 13).

Goetz et al. fails to teach a method of (a) storing in a data processing system patient medication information including medication distribution information obtained from a health care provider and (b) comparing the patient medication information to a database to identify profile information.

Hacker teaches a method of (a) storing in a data processing system patient medication information including medication distribution information obtained from a health care provider (column 8, lines 4 – 13 and column 7, lines 51 – 54) and (b) comparing the patient medication information to a database to identify profile information (column 11, lines 19 – 31).

The motivation for combining the teachings of Goetz et al. and Hacker is discussed in the rejection of claim 8, and incorporated herein.

In regard to claim 16, Goetz et al. teaches a method of generating a medical profile as per claim 15.

Goetz et al. fails to teach a method wherein step (a) further comprises entering into the data processing system patient medication information including medication distribution information obtained from a plurality of health care providers.

Hacker teaches a method wherein step (a) further comprises entering into the data processing system patient medication information including medication distribution information obtained from a plurality of health care providers (column 8, lines 4 – 13).

The motivation for combining the teachings of Goetz et al. and Hacker is discussed in the rejection of claim 8, and incorporated herein.

In regard to claim 17, Goetz et al. teaches a method, as per claim 16, wherein in step (b) the profile information includes a severe side effect of the medication, a severe drug-drug interaction of the medication, and a therapeutic class of the medication (column 6, lines 45 –59).

In regard to claim 18, Goetz et al. teaches a method of facilitating the display of the patient medication information to a user other than the patient wherein the patient possesses information to access the data processing system in order to display the patient medication information and the patient provides the information to access the data processing system to the user so that the user accesses the data processing system in order to display the patient medication information (column 10, lines 28 - 31).

Goetz et al. fails to teach a method of providing medication information, comprising entering into a data processing system patient medication information

originating from a health care provider previously distributing medication to a patient.

Hacker teaches a method of providing medication information, comprising entering into a data processing system patient medication information originating from a health care provider previously distributing medication to a patient (column 8, lines 4 – 7).

The motivation for combining the teachings of Goetz et al. and Hacker is discussed in the rejection of claim 8, and incorporated herein.

In regard to claim 19, Goetz et al. teaches a method of providing medication information as per claim 18.

Goetz et al. fails to teach a method wherein step (a) further comprises entering into the data processing system patient medication information from a plurality of health care providers previously distributing medication to the patient.

Hacker teaches a method wherein step (a) further comprises entering into the data processing system patient medication information from a plurality of health care providers previously distributing medication to the patient (column 8, lines 4 – 13).

The motivation for combining the teachings of Goetz et al. and Hacker is discussed in the rejection of claim 8, and incorporated herein.

In regard to claim 20, Goetz et al. teaches a method of providing medication information.

Goetz et al. fails to teach a method further comprising: accessing a database containing medication specific characteristics; comparing the patient medication information and the medication specific characteristics; generating profile information; and displaying the profile information to the user.

Hacker teaches a method further comprising: accessing a database containing medication specific characteristics (column 7, lines 22 – 25); comparing the patient medication information and the medication specific characteristics (column 7, lines 51 – 60); generating profile information (column 11, 19 – 31); and displaying the profile information to the user (column 8, lines 4 – 13 and lines 57 – 59) where the server screens information for possible interactions.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method further comprising accessing a database containing medication specific characteristics; comparing the patient medication information and the medication specific characteristics; generating profile information; and displaying the profile information to the user as taught by Hacker with the motivation of enabling physicians and other health care providers the ability to determine if any drug-drug interactions or side effects are likely, based upon the information contained in the electronic medical record

as taught by Hacker with the motivation of allowing the user to verify prescriptions for potential drug-drug interactions (column 11, lines 19 – 31).

In regard to claim 21, Goetz et al. teaches a method, as per claim 20, wherein the profile information includes a severe side effect of the medication, a severe drug-drug interaction of the medication, and a therapeutic class of the medication (column 10, lines 45 – 59).

In regard to claim 22, Goetz et al. teaches a method, as per claim 18, wherein in step (a) patient medication information further comprises: a name of a medication in use by the patient (column 6, line 56), an administration dose of the medication (column 6, line 57), a name of a health care provider that prescribed the medication (column 6, line 61), an original date of a prescription for the medication (column 6, line 62), a set of instructions for administering the medication (column 6, line 60), and compliance information for the medication (column 6, lines 31 – 67). The invention disclosed by Goetz et al. claims that the memory will contain at least the information listed, therefore it would be obvious to include the exhaustion of a prescription.

Goetz et al. does not expressly show a date of exhaustion of the prescription for the medication.

However, this difference is only found in the nonfunctional descriptive material and does not alter the function of the method (i.e. the descriptive

material does not change the method). Thus, the descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983; *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a date of exhaustion of the prescription for the medication because it does not alter how the method functions and does not patentably distinguish the claimed invention.

In regard to claim 23, Goetz et al. teaches a medical information database, comprising: consequential information including identification of any drug-drug interactions of the prescribed medications (column 6, lines 45 – 48 and line 58).

Goetz et al. fails to teach a patient profile database including for each of a plurality of patients-a patient profile, including medication specific data on a plurality of medications which have been prescribed for the patient and a secured access to the patient profile database, requiring entry of patient, identification information and user password information in order for a user to gain access to the identified patient's profile.

Hacker teaches a patient profile, including medication specific data on a plurality of medications which have been prescribed for the patient (column 11, lines 19 – 31) and a secured access to the patient profile database, requiring

entry of patient, identification information and user password information in order for a user to gain access to the identified patient's profile (column 7, lines 24 – 25, lines 43 – 50; column 7, line 50 through column 8, line 17).

The motivation for combining the teachings of Goetz et al. and Hacker is discussed in the rejection of claim 4 and incorporated herein.

In regard to claim 24, Goetz et al. teaches a database, as per claim 23, wherein the consequential information further includes side effects of the medications (column 6, lines 45 – 58 and line 59).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- U.S. Publication No. 2002/0052760 (Munoz et al.) teaches a patient prescription historical data base, prescription request refill, drug delivery, dosage, and patient identification.
- U.S. Patent No. 7,072,840 (Mayaud) teaches a therapeutic preference and patient identification.
- U.S. Publication No. 2002/0032582 (Feeney et al.) teaches a method of medication tracking using a database, which can maintain prescriptions. Also includes the entry of scripts, inventory management, and receiving electronic prescription information.

- U.S. Publication No. 2003/0061074 (Dutta et al.) teaches a product, method and system for patient prescription information. Also tracks existing patient history.
- U.S. Publication No. 2004/0128162 (Schlotterbeck et al.) teaches a database of medication for various fields of medicine (pediatric, geriatric) including dosage, administration, and delivery of the medication.
- U.S. Publication No. 2002/0161607 (Subich) teaches a drug-tracking database including adverse events.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristine K. Rapillo whose telephone number is 571-270-3325. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Akm Ullah can be reached on 571-272-2361. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KKR

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